

FEB 19 2004

Philips Medical Systems North America

K040254

## 510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person:	Lynn Harmer
Telephone No.:	(425) 487-7312
Date prepared:	22 January 2003
Device (Trade) Name:	Integris 3D-RA, release 4.2
Regulation Name:	Picture archiving and communications system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	90 LLZ

### **Predicate Device:**

The Integris 3D-RA release 4.2 device is substantially equivalent to the Integris 3D-RA release 1 (FDA ref. K983877.)

### **Device Description:**

The Integris 3D-RA release 4.2 device allows the user to obtain a three dimensional impression of vasculature with a single contrast injection. This 3D impression is acquired by rotating the C-arm isocentrically around the region of interest. Exposures are made as the arteries in the region of interest are being filled. The set of 2-Dimensional images form the rotational angiographic examination and is transferred via DICOM connection to the 3D-RA workstation. A 3-Dimensional image is constructed from the delivered image information resulting in an object which can be viewed from almost any angle.

### **Indications for Use:**

The Integris 3D-RA release 4.2 device is intended to assist physicians when analyzing 2-Dimensional, DSA X-ray images by creating 3-Dimensional views from sets of 2-Dimensional images created during rotational angiographic runs.



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Tel: 425 487-7000

**General Safety and Effectiveness:**

The device and its labeling will comply with the applicable requirements of the federal performance standards (Code of Federal Regulations, Title 21, subchapter J – Radiological Health, parts 1020.10 and 1040.10). Additionally the Integris 3D-RA release 4.2 complies with the ACR/NEMA DICOM digital imaging communication standard.

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety UL 60950. All required documents and reports have been or will be supplied to the appropriate oversight agency to establish compliance with the applicable requirements.

**Conclusion:**

The Philips 3D-RA, release 4.2 does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Philips 3D-RA release 4.2 substantially equivalent with the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 19 2004

Philips Medical Systems  
North America Company  
% Mr. John So  
Senior Project Engineer/Program Reviewer  
Underwriters Laboratories, Inc.  
2600 NW Lake Road  
CAMAS WA 98607

Re: K040254  
Trade/Device Name: Philips Integris 3D-RA,  
release 4.2  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communication system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: February 3, 2004  
Received: February 4, 2004

Dear Mr. So:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

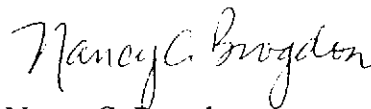
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) : K040254

Device Name : **Philips Integris 3D-RA release 4.2**

Indications For Use :

The Integris 3D-RA release 4.2 is intended to assist the physicians when analyzing 2-Dimensional, DSA X-ray images by creating 3-Dimensional views from sets of 2-Dimensional images created during rotational angiographic runs.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K040254